

REMARKS

Status of the Claims

Claims 1-2, 4-8, 10-50 and 52-79 are currently pending in the application. Claims 54 and 56 are amended with entry of this amendment. Claims 32-40, 52-53 and 65-67 were withdrawn by the Office. Claims 1-2, 4-8, 10-31, 41-50 and 54, 56-64 and 68-79 remain under consideration with entry of this amendment.

Summary

Claims 1-2, 4-8, 10-50 and 52-79 are pending in the application and were examined in the Office Action dated 30 June 2008. Applicants note with appreciation that the rejection of claims 1, 2, 4, 6, 10, 11, 13-31, 41-50, 57-63 and 68-79 under 35 U.S.C. §112, second paragraph, has been withdrawn. However, the Office has continued to assert the following claim rejections: (a) claims 1, 2, 4-6, 10-13, 17, 18, 23-30, 46-50, 54, 55, 57, 70, 71 and 76-78 remain rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,747,058 to Tipton et al. (“Tipton”); (b) claims 7, 8, 14-16, 19-22, 41-45, 58-62, 68-71, 73-76 and 79 remain rejected under 35 U.S.C. §103(a) as unpatentable over Tipton; and (c) claims 31, 63, 64 and 72 stand rejected under 35 U.S.C. §103(a) as unpatentable over Tipton. Applicants respectfully traverse all pending claim rejections for the following reasons.

Overview of the Amendment

Applicants, by way of this amendment, have amended claim 56 in order to recite the invention with greater particularity. Specifically, claim 56 have been amended to now recite that the solvent “possesses” an organic acid residue and an alcohol instead of just “comprising” such moieties in accordance with the helpful suggestion of the examiner. Support for the amendment can be found at Paragraph [0040] of the

specification as originally filed. Accordingly, no new matter is added by way of the amendment to claim 56, and the entry thereof is respectfully requested.

The Rejection under 35 U.S.C. §102(b)

Claims 1, 2, 4-6, 10-13, 17, 18, 23-30, 46-50, 54, 55, 57, 70, 71, and 76-78 stand rejected under 35 U.S.C. §102(b) as anticipated by Tipton. In particular, the Office asserts “Tipton discloses a composition comprising a HVLCM (with sucrose acetate isobutyrate specifically employed)” referring to the general disclosure of HVLCMs as a controlled release carrier (columns 2, 4, 5 and 8), and then refers specifically to the topical oral delivery composition described in column 12 of Tipton. Office Action at page 3. The Office then refers specifically to the topical oral delivery composition (the water/oil emulsion mouthwash) described in columns 11 and 12 of Tipton, and relates the surfactant component of the Tipton mouthwash to the network formers recited in applicants’ claims, and the oily component of the Tipton mouthwash to the rheology modifiers recited in applicants’ claims. Office Action at pages 3-4, bridging sentence. The Office then skips from the required water component of the Tipton mouthwash (column 12), to a list of viscosity lowering water soluble or miscible solvents including DMSO, ethyl lactate and triacetin (column 2), and asserts that this “meets the solvent requirement [of applicants’ claims]” (Office Action at page 4), before jumping to Tipton’s general list of drugs including codeine (column 7) and then declaring “the formulation of Tipton is placed in gelatin capsules for oral administration (claim 88)”. Office Action at page 4, emphasis added. The Office then concludes “the composition of Tipton would inherently possess [applicants’ recited properties].” Office Action at page 4, emphasis added. Applicants respectfully traverse the rejection for the following reasons.

In claim 1, applicants have recited and claimed a specific invention that has the following express elements: (a) an oral dosage form; (b) containing a formulation that forms a network within the formulation and an outer surface when contacted with an aqueous environment; (c) the formulation includes a drug; (d) the formulation includes a HVLCM; (e) the formulation includes a network former; (f) the formulation includes a

rheology modifier; and (g) the formulation includes a solvent. Claims 2-60 each depend, either directly or indirectly from claim 1 and thus also contain the express combination of these same 7 basic elements.

Claim 70 recites a specific invention that has the following express elements: (a) an oral dosage form; (b) containing a formulation; (c) the formulation includes a drug; (d) the formulation includes a HVLCM; (e) the formulation includes a network former; (f) the formulation includes a rheology modifier; (g) the formulation includes a solvent; and (h) each of the elements (c)-(g) are present in sufficient amounts to (i) reduce the rate of extraction of the drug from the formulation with solvent, while (j) simultaneously providing desirable release kinetics of the drug upon administration to a subject. Claims 71-76 each depend either directly or indirectly from claim 70 and thus also contain the express combination of these same 10 basic elements.

Claim 77 recites a specific invention that has the following 3 express elements: (a) a drug delivery device; (b) comprising a formulation; (c) where the formulation forms a network within the formulation and an outer surface of the formulation upon exposure to an aqueous environment.

Claim 78 recites a specific invention that has the following 7 express elements: (a) a drug delivery device; (b) comprising a formulation; (c) the formulation includes sucrose acetate isobutyrate (SAIB); (d) the formulation includes cellulose acetate butyrate (CAB); (e) the formulation includes isopropyl myristate (IPM); (f) the formulation includes ethyl lactate (EL); and (g) the formulation includes an opioid.

A claim is anticipated only if each and every element as set forth in the claim is described in a single prior art reference, that is, the identical invention must be shown in the prior art reference in as complete detail as is contained in the claim (see, e.g., *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051 (Fed. Cir. 1987); and *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913 (Fed. Cir. 1989)) and the elements must be arranged as required by the claim (see, e.g., *In re Bond*, 15 USPQ2d 1566 (Fed Cir. 1990)). For a recited combination, the identical invention is the express combination (not some different combination), and if a reference fails to highlight a particular mixture or combination, among the many other mixtures disclosed, that reference fails to

anticipate (*In re Kollman et al.* 201 USPQ 193 (CCPA 1979)), and where one skilled in the art would have to choose judiciously from a number of different possible combinations, that reference likewise fails to anticipate (*In re Sivaramakrishnan* 213 USPQ 441 (CCPA 1982)). Furthermore, the basis on which anticipation is measured is whether or not the prior disclosure is an “enabled disclosure” and this is particularly important when a theory of inherency is being used, as is the case in the instant rejection. *In re Samour*, 197 USPQ 1 (CCPA 1978).

For claims 1-60, in order to anticipate those claims Tipton would have to disclose applicants’ express mixture or combination, that is, the specific mixture containing all 7 required components in express combination. This is clearly not the case, since the Office has been forced to combine certain elements of an oil/water emulsion mouthwash composition (a particular mixture described in columns 11 and 12), with bits and pieces of a totally disconnected generic disclosure of pharmaceutically acceptable solvents (column 2), and then further has tried to match this improper combination with yet another totally disconnected summary disclosure of drugs (column 7), and then further tried to match that improper series of combinations with still another totally disconnected claim to a gelatin capsule (claim 88). The Office then seems to just wave its’ hands and conclude that its piecemeal combination of disparate parts of Tipton would somehow provide a formulation that would have applicants’ recited property of forming a network on exposure to aqueous environments since “the composition of Tipton would inherently possess [that] characteristic” Office Action at page 4.

In relying upon a theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to support the determination that an allegedly inherent characteristic necessarily flows from the teachings of the prior art. *Ex parte Levy* 17 USPQ2d 1461 (BPAI 1990). The fact that a prior art composition may inherently have the characteristics of a recited product is not sufficient. *Ex parte Skinner* 2 USPQ2d 1788 (BAPI 1986). Inherency must be a necessary result and not a merely possible result. *In re Oelrich* 212 USPQ 323 (CCPA 1981); and *Ex parte Keith et al.* 154 USPQ 320 (POBA 1966). In the case of the Office’s inherency theory, there is no single composition recited by Tipton that would qualify as the Tipton composition that would

inherently possess applicants' recited properties. The Office has improperly cobbled together completely disconnected portions of the Tipton reference, and has then improperly concluded that "the Tipton composition" would inherently possess applicants' recited properties. There is simply no support for the Office's assertions. The identical invention (applicants' expressly recited combination) simply does not exist in Tipton. The mouthwash of Tipton would not "inherently" possess applicants' recited properties. And there is clearly no enabling disclosure of applicants' recited invention.

Accordingly, the rejection of claims 1, 2, 4-6, 10-13, 17, 18, 23-30, 46-50, 54, 55 and 57 under 35 U.S.C. §102(b) is improper. Reconsideration and withdrawal of the rejection is thus earnestly solicited.

In order to anticipate claims 70, 71 and 76, Tipton would have to disclose applicants' express mixture or combination, that is, the specific mixture containing all 10 required components in express combination. Here again, the Office has clearly failed to identify the identical invention in Tipton, relying instead upon the improper piecemeal combinations of oil/water emulsion mouthwash compositions with disassociated generic disclosures and claims. Accordingly, the rejection of claims 70, 71 and 76 under 35 U.S.C. §102(b) is improper. Reconsideration and withdrawal of the rejection is thus earnestly solicited.

In order to anticipate claim 77, Tipton would have to disclose the identical composition to applicants' recited composition and would further have to establish that that particular composition would inherently possess applicants' recited properties. The Office instead seems to just conclude that "the formulation" of Tipton might inherently possess applicants' recited properties. The burden of proof for any assertion of inherent anticipation is exceptionally high. The fact that a certain result or characteristic may occur, or may be present in the prior art is simply not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be

so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999), emphasis added. The Office has provided no support for its’ theory of inherency whatsoever, and has therefore not met its’ burden of proof. Accordingly, the rejection of claim 77 under 35 U.S.C. §102(b) is improper. Reconsideration and withdrawal of the rejection is thus earnestly solicited.

In order to anticipate claim 78, Tipton would have to disclose applicants’ express mixture or combination, that is, the specific mixture containing all 7 required components in identical combination. Here again, the Office has clearly failed to identify the identical invention in Tipton, relying instead upon the improper piecemeal combinations of oil/water emulsion mouthwash compositions with disassociated generic disclosures and claims. Accordingly, the rejection of claim 78 under 35 U.S.C. §102(b) is improper. Reconsideration and withdrawal of the rejection is thus earnestly solicited.

The Rejections under 35 U.S.C. §103(a)

Claims 7, 8, 14-16, 19-22, 41-45, 58-62, 68-71, 73-76 and 79 stand rejected under 35 U.S.C. §103(a) as obvious over Tipton. In particular, the Office asserts that Tipton “describes compositions that contain CAB and HVLCM and solvents separately”, yet the Office acknowledges that Tipton “does not disclose one composition that has HVLCM, CAB, solvent and rheology modifier”. Office Action at page 7. However, on the basis that Tipton “teaches the components separately” the Office concludes that “it would be obvious to combine two compositions to form a third composition that would be used for the same purpose.” Office Action at pages 7 and 8. The Office supports this position in part by asserting “it would be obvious to place the formulation [of Tipton] in soft or hard gelatin capsules for delivery” (Office Action at page 7), and that Tipton formulated CAB with SAIB to influence release of active agent as shown in figures 4, 6, 11, 13, and 15. Office Action at page 8. Applicants respectfully traverse the rejection for the following reasons.

When considering the patentability of claims under Section 103, the following tenets of patent law must be adhered to: (a) the claimed invention must be considered as a whole; (b) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (c) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (c) reasonable expectation of success is the standard with which obviousness is determined. *Hodosh v. Block Drug Co., Inc.*, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

In the instant rejection, the Office has acknowledged that Tipton fails to disclose applicants' recited invention. In addition, applicants have established herein above that Tipton likewise fails to disclose the base combination of each and every independent claim under prosecution. The Office has tried to make up for this failure by asserting that it would be obvious to: (a) modify Tipton's oil/water emulsion mouthwash composition from columns 11 and 12, with certain unrelated generic disclosures from other parts of the document in order to arrive at applicants' recited compositions. The Office has not been able to point to any basis for the assertion that when Tipton is considered as a whole, it would somehow teach this particular modification. In fact, the only arguments that are provided are: (a) it would be obvious to place Tipton's modified mouthwash emulsion in a gelatin capsule for administration; and (b) it would be obvious to modify Tipton's mouthwash with varying amounts of CAB since it was shown that CAB influenced release of the active agent from the SAIB matrix.

Turning to the first of the above-noted "motivations" proposed by the Office, applicants note that a mouthwash is intended for application in the mouth, not from the stomach. Putting a mouthwash into a capsule or pill for swallowing defies all common sense. If one were to do so, they would obviously frustrate the entire purpose of the mouthwash (to help against bad breath) since the entire formulation would be swallowed. Turning the second of the above-noted "motivations" proposed by the Office, applicants have recited oral dosage formulations. Once swallowed, an oral dosage formulation takes 24 hours to pass through the digestive system and any remaining formulation is then excreted in the stool. The Office has pointed to Figures 4, 6, 11, 13 and 15 of Tipton where CAB was used to influence release of an active from a SAIB matrix. Figure 4 of

Tipton shows delivery of about 50-60% of the total active agent over the period of 144 hours (6 days). Figure 6 of Tipton shows delivery of up to 25 mg of active agent over the period of 192 hours (8 days). Figure 11 of Tipton shows that without CAB, the SAIB formulation released 80% of the active agent within 24 hours, but the addition of CAB caused the system to release only about 40% of the active agent after 144 hours (6 days). Figure 13 of Tipton shows continuous, increasing delivery of the active agent from two CAB compositions through about 144 hours (6 days), (note the mass balance issue with 130% release). Finally, Figure 15 of Tipton shows continuous, increasing delivery of the active agent through 72 hours (3 days). The Office asserts that the skilled person would view these data, somehow know to make significant modification to Tipton's oil/water emulsion mouthwash formulation to somehow arrive at applicants' recited combinations, and that all of this would flow from the understanding that CAB retards delivery of an active agent from a SAIB matrix. With respect, what the Office is asserting is that the skilled person would intentionally design a mouthwash for delivery by swallowing a capsule, and would further design that dosage form to continue delivering the active agent from the toilet or the sewer, up to 7 days after the dosage form has passed through the entire digestive system.

Clearly, the Office's proposed modifications to Tipton's mouthwash are improper since they frustrate the basic purpose of the composition being modified. This is strong evidence of nonobviousness as noted by the Supreme Court in *KSR*, where the Supreme Court found that consideration of prior art that teaches away from the claimed invention is also relevant to the determination of obviousness. In particular, the Court stated that "when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007). See also, *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, where the Federal Circuit stated that "[once] all claim limitations are found in a number of prior art references, the factfinder must determine '[w]hat the prior art teaches, whether it teaches away from the claimed invention, and whether it motivates a combination of teachings from different references.' *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1641, 1646 (Fed. Cir. 2006), citing *In re Fulton*, 391

F.3d 1195, 1199-1200 (Fed. Cir. 2004) (emphasis added). Finally, as stated in the MPEP, “[i]f [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. M.P.E.P § 2143.01. The Federal Circuit has stated a similar principle in *In re Gordon*, indicating that where the proposed modification would render the prior art invention unsatisfactory for its intended purpose, the prior art invention effectively teaches away from the proposed modification. *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984).

For all of the above reasons, then, the Office has failed to establish obviousness with its’ proposed modification of the Tipton reference. When applicants’ claimed invention is considered as a whole, it is clear that the express combination recited by applicants’ claims is simply not present. This point has already been acknowledged by the Office. When the Tipton reference is considered as a whole, it is clear that it simply does not suggest the desirability and thus the obviousness of making the combinations recited by applicants’ claims. The only possible way that the Office can arrive at applicants’ expressly recited combinations is by cobbling together completely unrelated portions of the Tipton disclosure using impermissible hindsight reconstruction, and then asserting a theory of inherency. The Office’s proposed modifications would render the Tipton mouthwash composition inoperative, and the Office’s proposed motivations are thus technically incorrect. Finally, there can simply be no reasonable expectation of success for the Office’s proposed modifications since they render the prior art material inoperative for their intended purposes.

In short, the Office has failed to establish a *prima facie* case of obviousness over Tipton since the Office fails to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the specific composition recited in applicants’ claims, having applicants’ unique performance characteristics, and would have had a reasonable expectation of success in doing so. Accordingly, applicants respectfully submit that the rejection of claims 7, 8, 14-16, 19-22, 41-45, 58-62, 68-71, 73-76 and 79 under 35 U.S.C. §103(a) as obvious over Tipton is improper. Reconsideration and withdrawal of the rejection is thus earnestly solicited.

Claims 31, 63, 64 and 72 remain rejected under 35 U.S.C. §103(a) as obvious over Tipton. In support of its rejection, the Office merely asserts “one of the drugs in Tipton is codeine, which is an opioid ... Tipton does not teach oxycodone ... [but] since oxycodone and codeine are opioids ... it is *prima facie* obvious that oxycodone can be used in place of codeine.” Office Action at page 9. Applicants respectfully traverse the rejection for the following reasons.

As established herein above, the Office has clearly failed to establish *prima facie* obviousness of applicants’ base recited combinations over Tipton. Simply arguing that Tipton teaches the administration of opioids fails to overcome the basic failure of that incomplete and improper showing. Applicants are unaware of any mouthwashes that contain an opioid. Mouthwashes are delivered by direct application into the oral cavity and swishing the liquid around in the mouth so as to cover as much of the cavity as possible, after which any mouthwash that remains is expectorated. It is therefore questionable at best if any skilled person would consider delivery of an opioid in this manner, and applicants submit that they simply would not.

Accordingly, the Office has failed to establish a *prima facie* case of obviousness over Tipton since the Office fails to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the specific composition recited in applicants’ claims, having applicants’ unique performance characteristics, and would have had a reasonable expectation of success in doing so. Accordingly, applicants respectfully submit that the rejection of claims 31, 63, 64 and 72 under 35 U.S.C. §103(a) as obvious over Tipton is improper. Reconsideration and withdrawal of the rejection is thus earnestly solicited.

CONCLUSION

Applicants submit that the pending claims define an invention that is both novel and nonobvious over the cited art, and thus all claims are in condition for allowance. Acknowledgement of this by the Office in the form of an early allowance is thus

respectfully requested. In addition, if the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, applicants invite the Examiner to contact the undersigned at (408) 777-4915.

Respectfully submitted,



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